

Remarks

As discussed herein, Applicants respectfully request reconsideration and withdrawal of the rejections of record.

Status of the Claims, and Amendment thereto

Claims 1-7 are pending and stand rejected by the Examiner. Claim 1 is respectfully requested to be amended as indicated herewith. Reconsideration and withdrawal of the rejections of claims 1-7 is respectfully requested.

Amended claim 1 adds no new matter, and merely adds clarification that Applicant's invention is directed to a method wherein the bodily fluid sample is an individual sample, taken at a single time, which is clearly supported by the original specification and claims. See in particular page 5, Example 1. In this example, it is specified that the samples of saliva, blood, or urine may be taken "at any time", clearly indicating that the samples are measured at any one time point of collection, rather than the samples from multiple time points being pooled.

Anticipation Rejection

Claims 1-7 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Xie. Applicants respectfully disagree. Xie teaches administration of a dose of racemic mephenytoin to patients, and collecting their urine to measure the relative amounts of (S) and (R) mephenytoin. However, unlike the present invention, Xie teaches that the urine is collected from these patients during the entire 8 hour period post-administration, and pooled for analysis. In the present case, Applicants claim an improved and simplified method of testing for a patient's 2C19 status by taking a single urine, plasma, or saliva sample from the patient. This offers the significant advantage of the patient not having to collect multiple samples, nor to collect samples over the entirety of an 8 hour period. Before Applicants' invention, it was not known that use of a single sample would provide an adequately accurate result for phenotyping a subject's 2C19 status. Therefore, it is respectfully submitted that this rejection has been overcome by the amendment to claim 1 herewith.

Obviousness Rejection

Claim 2 stands rejected under 35 U.S.C. §103 as allegedly being obvious over Xie in view of Fitzpatrick. Applicants respectfully disagree. As discussed above, Applicants have demonstrated the patentability of the present claims over Xie. Just as Xie does not anticipate claims 1-7, the combination of Xie with Fitzpatrick does not obviate claim 2.

It is respectfully submitted that the Examiner has not made a prima facie case of obviousness. The Examiner fails to cite any motivation for those of ordinary skill in the art to combine the teachings of Xie and Fitzpatrick. Moreover, it is respectfully submitted that there is no such motivation. Xie involves the testing of patients using mephenytoin to determine their 2C19 status. Fitzpatrick makes no mention of mephenytoin, CYP2C19, cytochrome, or even anything about testing patients to determine their metabolic status with respect to any drugs or compounds. Simply put, there is little in common between these two documents, and neither of them contains any suggestion that would lead those of skill in the art to combine one with the other.

Furthermore, even if one were to combine the teachings of Fitzpatrick with the method taught by Xie, one would only learn that saliva might be tested for mephenytoin metabolites, in addition to plasma and urine. There still would be no teaching or suggestion that the 2C19 status of a patient could be accurately determined from a single fluid sample taken at a single time point, as opposed to the Xie teaching of collecting samples during the entire 8 hour post-administration period. Therefore, even when Xie and Fitzpatrick are combined (despite the lack of suggestion in the prior art), one still does not achieve the presently claimed invention.

Conclusion

In view of the above, Applicants respectfully submit that all of the pending claims are allowable in their present form, and that the application is otherwise in condition for allowance. The Examiner is respectfully requested to withdraw the rejections and, as the next official action, to provide a Notice of Allowance.

If any issues remain which can be resolved by a telephone conference, or should the Examiner have any questions or comments regarding this matter, the Examiner is respectfully invited to contact the undersigned at the telephone number shown below.

The Commissioner is hereby authorized to charge any additional fees required, or to credit any overpayment, to Deposit Account No. 16-1445.

Respectfully submitted,

Date:

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